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21 CFR Ch. I (4–1–05 Edition)

applicable sections of parts 101 and 130 of this chapter.

[46 FR 9934, Jan. 30, 1981, as amended at 47 FR 11822, Mar. 19, 1982; 47 FR 41523, Sept. 21, 1982; 48 FR 24869, June 3, 1983; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.115 Concentrated milk.

(a) *Description.* Concentrated milk is the liquid food obtained by partial removal of water from milk. The milkfat and total milk solids contents of the food are not less than 7.5 and 25.5 percent, respectively. It is pasteurized, but is not processed by heat so as to prevent spoilage. It may be homogenized.

(b) *Vitamin addition* (Optional). If added, vitamin D shall be present in such quantity that each fluid ounce of the food contains 25 International Units thereof, within limits of good manufacturing practice.

(c) *Optional ingredients.* The following safe and suitable optional ingredients may be used:

(1) Carrier for vitamin D.

(2) Characterizing flavoring ingredients, with or without coloring, as follows:

(i) Fruit and fruit juice, including concentrated fruit and fruit juice.

(ii) Natural and artificial food flavoring.

(d) *Methods of analysis.* Referenced methods are from “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877–2504, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) Milkfat content—“Fat—Official Final Action,” section 16.172.

(2) Total milk solids—“Total Solids—Official Final Action,” section 16.169.

(3) Vitamin D content—“Vitamin D in Milk—Official Final Action,” sections 43.195–43.208.

(e) *Nomenclature.* The name of the food is “Concentrated milk” or alternatively “Condensed milk”. If the food contains added vitamin D, the phrase “vitamin D” or “vitamin D added” shall accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half the height of the letters used in such name. The word “homogenized” may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 47 FR 11822, Mar. 19, 1982; 48 FR 13024, Mar. 29, 1983; 49 FR 10090, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.120 Sweetened condensed milk.

(a) *Description.* Sweetened condensed milk is the food obtained by partial removal of water only from a mixture of milk and safe and suitable nutritive carbohydrate sweeteners. The finished food contains not less than 8 percent by weight of milkfat, and not less than 28 percent by weight of total milk solids. The quantity of nutritive carbohydrate sweetener used is sufficient to prevent spoilage. The food is pasteurized and may be homogenized.

(b) *Optional ingredients.* The following safe and suitable characterizing flavoring ingredients, with or without coloring and nutritive carbohydrate sweeteners, may be used:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavoring.

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in “Official Methods of Analysis of the Association of Official Analytical Chemists,” 13th Ed. (1980), section 16.185, under “Fat—Official Final Action,” which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481

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North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(d) *Nomenclature.* The name of the food is "Sweetened condensed milk." The word "homogenized" may appear on the label if the food has been homogenized. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[43 FR 21670, May 19, 1978, as amended at 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.125 Nonfat dry milk.

(a) *Description.* Nonfat dry milk is the product obtained by removal of water only from pasteurized skim milk. It contains not more than 5 percent by weight of moisture, and not more than 1½ percent by weight of milkfat unless otherwise indicated.

(b) *Optional ingredients.* Safe and suitable characterizing flavoring ingredients (with or without coloring and nutritive carbohydrate sweetener) as follows:

(1) Fruit and fruit juice, including concentrated fruit and fruit juice.

(2) Natural and artificial food flavorings.

(c) *Methods of analysis.* The following referenced methods of analysis are from "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or

go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) Milkfat content—"Fat in Dried Milk—Official Final Action," sections 16.199–16.200.

(2) Moisture content—"Moisture—Official Final Action," section 16.192.

(d) *Nomenclature.* The name of the food is "Nonfat dry milk". If the fat content is over 1½ percent by weight, the name of the food on the principal display panel or panels shall be accompanied by the statement "Contains __% milkfat", the blank to be filled in with the percentage to the nearest one-tenth of 1 percent of fat contained, within limits of good manufacturing practice. The name of the food shall include a declaration of the presence of any characterizing flavoring, as specified in § 101.22 of this chapter.

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14360, Mar. 15, 1977, as amended at 43 FR 19836, May 9, 1978; 47 FR 11823, Mar. 19, 1982; 49 FR 10091, Mar. 19, 1984; 54 FR 24892, June 12, 1989; 58 FR 2890, Jan. 6, 1993]

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

(a) *Description.* Nonfat dry milk fortified with vitamins A and D conforms to the standard of identity for nonfat dry milk, except that vitamins A and D are added as prescribed by paragraph (b) of this section.

(b) *Vitamin addition.* (1) Vitamin A is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 2000 International Units thereof.

(2) Vitamin D is added in such quantity that, when prepared according to label directions, each quart of the reconstituted product contains 400 International Units thereof.

(3) The requirements of this paragraph will be deemed to have been met if reasonable overages, within limits of good manufacturing practice, are present to ensure that the required levels of vitamins are maintained throughout the expected shelf life of